

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Statement of the Interview

The Applicants' representative, Christian M. Bauer, appreciates the Examiner's time during the telephonic interview conducted 8 January 2008. Discussions focused on the double-patenting rejection and the Examiner's Response to the Applicants' arguments in the 20 September 2007 Final Office Action. Also discussed was Applicants' intent to clarify the language of claim 1.

II. Status of the Claims

Claim 73 was cancelled previously. Claim 1 is amended to clarify the language of "smaller T_{\max} " to a "shorter time to T_{\max} " and "when compared to a T_{\max} of" to "when compared to the time to T_{\max} of." This amendment clarifies that the value of T_{\max} is not decreased, but the time to reach T_{\max} is decreased. Exemplary support can be found in the original specification, at page 14, lines 4-10. Claims 2, 31, and 51 are amended to delete the phrase "a semi-amorphous phase, and mixtures thereof," thereby setting forth the subject matter more clearly.

Applicants acknowledge the finality of the present Office Action. Because the amendments to the claims do not introduce any new matter or require additional search, and because the amendments place the application in condition for allowance, Applicants respectfully request entry of the amendment for the purpose of appeal. Upon entry, claims 1-72 are pending in the application.

III. Double Patenting Rejection

Claims 1-26 and 31-72 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-34 of U.S. Patent No. 6,908,626 to Cooper *et al.* in view of U.S. Patent No. 6,221,377 to Meyer *et al.* Applicants respectfully traverse the rejection.

Claim 1 of the present application recites the transition phrase “comprising” thus allowing the scope of the claim to be open to include other elements, for example, those elements recited in claim 1 of the ‘626 patent. Applicants note that because of this, the instant claims may be interpreted as “dominating” certain features of the ‘626 patent claims. MPEP § 804.II provides that domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. *In re Kaplan*, 789 F.2d 1574, 1577-78, (Fed. Cir. 1986). In other words, even though the claims of the instant application may dominate some claims of the ‘626 patent, domination, by itself, is not *per se* double patenting. The Office Action must still determine whether the later-filed claims are patentably distinct from the earlier-cited patent claims.

The determination of whether an obviousness-type double patenting rejection is proper requires two steps. First, the Examiner must construe the claim(s) in the earlier patent and the claims at issue in the later patent application and determine the differences. Second, the Examiner must then determine whether the identified differences render the claims in the later-filed patent application *patentably distinct*. See MPEP § 804.II.B.1.

The double patenting rejection in the instant application is in error because A) the Office Action failed to identify all the differences between the claims of the ‘626 patent and claim 1 of the instant application and therefore fails to explain why these differences are obvious, and B) for the one difference identified in instant claim 1, the Office Action failed to provide a reason that such a difference is an obvious variation over the scope of the claims of the ‘626 patent.

A. The Office Action failed to identify all the differences between the claims of the '626 patent and the instant application and thus failed provide reasons why those unidentified differences are obvious

Claim 1 of the '626 patent is reproduced in its entirety below:

1. A formulation comprising: (a) at least one population of nanoparticulate of at least one poorly soluble active agent having an effective average particle size of less than about 1 micron; (b) at least one surface stabilizer adsorbed onto the surface of the nanoparticulate active agent particles wherein the concentration of the surface stabilizer is from about 0.5% to about 99.999%(w/w), based upon the total weight of the nanoparticulate active agent and the surface stabilizer, and wherein the surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and an ionic surface stabilize; and (c) *at least one population of microparticulate active agent, which is either the same as or different from the active agent of (a), and having an effective average particle size of greater than about 1 micron and less than about 10 microns* wherein the concentration of the microparticulate agent is from about 5% to about 85%, based upon the total weight of the microparticulate active agent, nanoparticulate active agent, and surface stabilizer.

(Emphasis added.)

A difference the Office Action failed to identify between instant claim 1 and the claims of the '626 patent is that claim 1 of the '626 patent requires the element: "(c) at least one population of microparticulate active agent . . . having an effective average particle size of greater than about 1 micron and less than about 10 microns." (See italicized language in claim 1 of the '626 patent above.) Because this difference was not identified, the double patenting rejection also failed to complete the second, required analysis under a double patenting rejection: That is, the rejection also lacks a discussion of how the elimination of this element in claim 1 of the '626 patent is an obvious variation over claim 1 of the present application. The Office Action has not complied with the MPEP requirements for determining whether a double patenting rejection is proper. For

at least this reason, claim 1 of the present patent application is patentably distinct from the claims of the '626 application. Withdrawal of the double patenting rejection is respectfully requested.

B. The Office Action fails to provide a reason that the identified difference is an obvious variation of the scope of the claims of the '626 patent

The one difference between claim 1 of the present application and that of the claims of the '626 patent that the Office Action did identify was: "the '626 patent does not expressly disclose meloxicam as an active agent." Office Action at page 3. The Office Action relies on Meyer for a teaching that meloxicam is an analgesic agent. The Office Action concludes that it would be obvious to modify the formulation of the '626 patent to include meloxicam as an active agent, because Meyer teaches that meloxicam is an analgesic and the '626 patent teaches that its formulation is suitable for analgesics.

Although the '626 patent teaches formulating analgesics into nanoparticles and meloxicam is an analgesic, the Office Action fails to provide a reason or rationale why one of ordinary skill in the art would select meloxicam out of all the compounds encompassed by the term "active agent" recited in the claims of the '626 patent. First, the fact that Meyer discloses that meloxicam is an analgesic provides no reason to select it from the plethora of compounds that are included within the term "active agent" according to the specification of the '626 patent. The '626 patent specification discloses at least 57 different sub-genus of "active agents". See claim 19. One of the 57 listed is analgesics. The sub-genus of analgesics itself includes four major classes of compounds: 1) paracetamol/NSAIDS, 2) COX-2 inhibitors, 3) opiates and morphinomimetics, and 4) specific agents. Within these classes there are many compounds, too numerous to list herein. Moreover, neither the '626 patent nor Meyer fairly teaches or suggest with a reasonable expectation of success which of these sub-genus, classes, or species of compounds are capable of being made into nanoparticles. As stated in the Oct. 10, 2007 Federal Guidelines for Determining Obviousness under 35 USC 103 in view of *KSR*, there must be some finite number of identified, predictable potential compounds that one of ordinary skill in the art would have pursued with the reasonable expectation of success. The Office Action has failed to

provide a reason that one of ordinary skill in the art would select meloxicam from the infinite number of identified, potential compounds listed in the '626 patent.

The Office Action has failed to identify all the differences between the claims of the '626 patent and the instant application, and for the one difference that the Office Action did identify, the Office Action failed to provide a reason that one of ordinary skill in the art would select meloxicam from the plethora of compounds defined as "active agents" in the claims of the '626 patent.

Accordingly, the claims of the instant application are patentably distinct from the claims of the '626 patent. The double patenting rejection is respectfully requested to be withdrawn.

IV. Rejection of Claims under 35 U.S.C. §103

Claims 1-17, 26-42 and 50-67 remain rejected for allegedly being obvious over WIPO Publication No. WO 93/25190 to Liversidge *et al.* ("Liversidge") or U.S. Patent No. 6,375,986 to Ryde *et al.* ("Ryde") in view of U.S. Patent No. 6,221,377 to Meyer *et al.* ("Meyer").

A. Prosecution History Summary

1. The Original Rejections: § 112 and § 103

The 26 January 2007 non-final Office Action rejected the claims under § 112, as lacking a written description and as not enabled. At the same time, the Office Action acknowledged that Liversidge does not expressly teach the claimed release profile (Page 4) and that Ryde does not expressly teach the claimed release profile (Page 6). However, the Office Action concludes that absent evidence to the contrary, the burden is shifted to the applicants to show that Liversidge (or Ryde) does not have the claimed release property (Page 5). Meyer is merely cited for a showing that meloxicam is an oxicam or NSAD.

2. Applicants' 26 June 2007 Response

Applicants responded to the § 112 rejections stating that if they were based upon the specification failing to disclose how to measure C_{\max} and T_{\max} values of a composition, Applicants stated that C_{\max} and T_{\max} are known pharmacokinetic properties that one of ordinary skill in the art would typically know how to identify when studying a drug composition. Thus, there is no need for the specification to explain the techniques to measure these values.

Alternatively, if the lack of a written description rejection was based upon the specification failing to disclose the claimed release profile values, Applicants cited paragraph [0025] of the specification as providing written support thereof. Likewise, if the lack of enablement rejection was based upon the specification failing to disclose how to prepare a composition with the claimed release profiles, Applicants cited paragraph [0018]-[0114] and Examples 1-3. See Page 29 of Applicants Response Dated 26 June 2007.

With respect to the obviousness rejections, Applicants responded by pointing out that the rejection is based upon a combination of references, that even when combined, failed to teach each and every limitation of the claimed invention, namely, the claimed release profiles (e.g., T_{\max} and C_{\max}). In addition, Applicants argued that the Office Action appears to base its rejection upon a conclusion that the release profiles are inherent, and if so, the Applicants requested a finding, a technical reasoning or fact, to that effect in accordance with MPEP §§ 2163.07 and 2112IV.

3. The 20 September 2007 Final Office Action

The final Office Action has acknowledged that Liversidge does not expressly teach the claimed release profile (Page 4) and that Ryde does not expressly teach the claimed release profile (Page 6). Despite Applicants' challenge that the rejection provides no basis for a finding that the claimed release profiles are inherent, the Final Office Action maintains its position based upon the following two statements:

First, at page 9, the final Office Action supports its finding of inherency by stating the premise that “where the claimed and prior art products are identical or substantially identical in structure or function, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.” (citing to *In re Best*, 562 F.2d 1252 (CCPA 1977)). The final Office Action then asserts that Liversidge (or Ryde) teaches similar nanoparticulate formulations with the same particle size and surface stabilizers; therefore the properties desired by the applicant are necessitated by the nanoparticles having the same effective average particle size with the use of the same surface stabilizer. Thus, the Office Action reasserts that properties desired by Applicants are necessarily contained with the formulation taught by Liversidge (or Ryde).

Second, the Office Action supports its finding of inherency by misconstruing a statement made by the Applicants. At page 11, the final Office Action quotes the Applicants where they stated that C_{\max} and T_{\max} are known pharmacokinetic properties that one of ordinary skill in the art would typically identify when studying a drug composition. From this statement, however, the final Office Action incorrectly concluded that Applicants admitted one of ordinary skill in the art would have been motivated by Liversidge (or Ryde) to obtain C_{\max} and T_{\max} within the claimed range.

V. The Applicants’ Response to the Final Office Action Statements

Even with the addition of the above statements, the Office Action still fails to provide support for its finding that the claimed release profiles are inherent properties. These statements fail to provide a basis in fact and/or technical reasoning to reasonably support that the claimed release profiles necessarily flows from the teaching of Liversidge or Ryde in combination with Meyer.

- A. Statement 1 (final Office Action Pages 9 and 10):** Liversidge (or Ryde) teaches similar nanoparticulate formulations with the same particles size and surface stabilizers; therefore the properties desired by the applicant are necessitated by the

nanoparticles having the same effective average particle size with the use of the same surface stabilizer.

The Applicants respectfully disagree.

First, the claimed invention, except for the allegedly inherent release profiles, does not exist in the prior art. Rather, the Office Action must construct the claimed invention from a combination of references, which when combined, still fails to fairly teach or suggest the claimed release profiles. For example, the Office Action admits that neither Liversidge nor Ryde teach the claimed release profile or the claimed meloxicam (See Pages 4-6 of the 20 September 2007 Office Action). Only with the combination of Meyer is the claimed meloxicam present. The invention only exists as a combination of prior art references selected by the Examiner (arguably using the Applicants' claims as a roadmap). Thus, the prior art formulation does not exist, except for the Examiner's construct. There is nothing in the prior art to compare with the claimed invention in order to support the Office Action conclusion that the claimed release profile is inherent in a nanoparticulate meloxicam composition.

Second, as stated above, neither Liversidge, Ryde, nor Meyer fairly teach or suggest the claimed release profile for a nanoparticulate meloxicam. To maintain that the claimed release profiles are inherent, the Office Action is speculating that the claimed release profile would result if the meloxicam of Meyer were formulated as taught by Liversidge or Ryde.

Instructive to this point is a recent non-precedential decision by the Board of Patent Appeals and Interferences. In *Ex Parte Kalliokulju*, WL 1378833, Appeal No. 2007-0834 (BPAI May 10, 2007), the BPAI reversed the Examiner's obvious rejection based upon a combination of two references, which when combined, taught all but one element of the claimed invention. A copy of this decision is submitted herewith as Exhibit A. The Examiner asserted that the still missing element was inherently taught by one of the references. The Board found that neither reference contained a specific teaching or suggestion that fairly meets the claim language; and that to affirm the rejection, would require speculation on the Board's part. The Board, citing the

Federal Circuit in *In re Roberston*, 169 F.3d 743 (Fed. Cir. 1999), emphasized that inherency cannot be established by mere probabilities or possibilities. Thus, the Board concluded that the references cited by the Examiner failed to support the allegedly inherent limitation of the applicant's claims.

Finally, the Office Action has not shown factual support or adequate reasoning for believing that the prior art combination product would necessarily have the claimed release profile. The Office Action rejection relies on its observation that the prior shows a similar (but admittedly not identical) formulation compared to that of the claimed invention, but for the claimed release profiles. Because of this similarity, the Office Action concludes that the claimed release profiles are inherent. As discussed above, the invention does not exist in the prior art, but for the Examiner's construct from a combination of references. The Office Action is therefore not in the position to invoke the cited rule of law in *In re Best*.

Instructive to this point is the non-precedential decision by the Board of Patent Appeals and Interferences in *Ex Parte Ahluwalia*, WL 33147783, Appeal No. 1997-1717 (BPAI January 1, 1997). A copy of this decision is submitted herewith as Exhibit B. In *Ex Parte Ahluwalia*, the BPAI reversed the Examiner's obviousness rejection stating that the rejection was devoid of factual support or adequate reasoning and thus improperly invoked the rule of law stated in *In re Best* (and cases cited therein). The Examiner's rejection was based on three references that disclosed compounds of similar structure to that of the claimed compound. Because of this similarity, the Examiner concluded that these prior art compounds must therefore inherently possess the claimed activity of applicant's inventive compound. Although the compounds of the prior art and the claimed invention were similar in structure and composition, there was nothing in the rejection that factually supported or adequately reasoned the Examiner's conclusion: that the prior art compounds inherently possessed the claimed activity. For this reason, the Board reversed the rejection.

- B. Statement 2 (final Office Action Page 11):** Applicants admitted one of ordinary skill in the art would have been motivated by Liversidge (or Ryde) to obtain C_{\max} and T_{\max} within the claimed range.

The Office Action misconstrues the Applicants' response to the § 112 rejections by concluding that Applicants statements provide the motivation to manipulate the formulations of Liversidge or Ryde such that their formulations would have the claimed release profiles.

As stated above, the Applicants stated that if the § 112 rejections were based upon the specification failing to disclosure how to measure C_{\max} and T_{\max} values of a composition, Applicants acknowledged that C_{\max} and T_{\max} are known pharmacokinetic properties and that one of ordinary skill in the art would typically know how to identify them when studying a drug composition. The fact that one of ordinary skill in the art would know how to measure C_{\max} and T_{\max} is not indicative of formulating a nanoparticulate meloxicam composition having the particularly claimed release profiles. This is akin to saying that because one knows how to measure the melting point of a solid, all melting points of compositions are obvious. Such a logical leap cannot be supported by the Applicants' statements or the knowledge of one of ordinary skill in the art.

The outstanding rejection is based upon a combination of references, which combination is acknowledge by the Examiner as failing to teach or suggest all the elements of the claimed invention, namely, the release profiles. The final Office Action has maintained the obviousness rejection alleging that the missing claimed release profiles are inherent in the prior art composition. The final Office Action provides two statements, discussed in detail above, as supporting its conclusion that the claimed release profiles are inherent in the prior art. Applicants have shown that the invention does not exist in the prior art, but for a hindsight construction based upon a combination of references. Applicants have also shown, and provided instructive BPAI decisions, that the additional statements supplied by the final Office Action are insufficient to shift the burden to the Applicants to show that the claimed release profiles are not

inherent. The claims are in a condition for allowance. Withdrawal of the rejection is respectfully requested.

VI. Rejection of claims 18-25, 43-49 and 68-73

Claims 18-25, 43-49 and 68-72 were rejected for allegedly being obvious over Liversidge or Ryde in view of WIPO Publication No. WO 01/45706 to Desai *et al.* ("Desai") or U.S. Patent No. 5,384,124 to Courteille *et al.* ("Courteille"). Applicants respectfully traverse the rejection.

Claims 18-25, 43-49 and 68-73 depend either directly or indirectly from claim 1 and are read to include the limitations of claim 1. Claim 1 was not rejected in view of Desai or Courteille. Because claim 1 is in a condition for allowance, the dependent claims are in a condition for allowance. Withdrawal of the rejection is respectfully requested.

VII. Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Atty. Dkt. No. 029318-1003
Appl. No. 10/784,900

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Jan 22, 2008

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The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JUHA KALLIOKULJU, ATTE LANSISALMI,
YOUSUF SAIFULLAH, and KHIEM LE

Appeal 2007-0834
Application 09/757,913
Technology Center 2100

Decided: May 10, 2007

Before JOHN C. MARTIN, HOWARD B. BLANKENSHIP, and
ST. JOHN COURTENAY III, *Administrative Patent Judges*.

COURTENAY, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 1-21.

THE INVENTION

The disclosed invention generally relates to relocating context information in header compression. More particularly, the disclosed

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invention is based on the idea that the context updating of the compressor and decompressor is stopped in both the mobile terminal and the old network entity, which ensures that both the mobile terminal and the old network entity use the same context, after which a snapshot of the compression and decompression context information is taken in the old network entity and transmitted to the new network entity to be stored therein. The mobile compressor compresses at least one header of at least one packet with the said context information and transmits the compressed at least one header of at least one packet to the new network entity. Then the new network entity decompresses the received at least one packet of the at least one header with the stored decompression context information. Because the context information has not changed during the relocation process, the compressor of the mobile terminal and the decompressor of the new network entity are automatically in synchronism and the data transfer can be continued (Specification 1 and 4).

Representative claim 1 is illustrative:

1. A method of relocating the header compression context in a packet network which transmits packets having compressed headers, said method comprising:

establishing a connection between a mobile terminal and a first network entity including storing context information used with compression and decompression of the headers of the packets at the mobile terminal and the first network entity;

stopping the context information updating in the mobile terminal and in the first network entity;

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taking a snapshot of the compression and decompression context information in the first network entity including storing said context information snapshot in the first network entity; and

changing the connection between the first network entity and the mobile terminal to a connection between the mobile terminal and a second network entity including transferring the context information snapshot stored by the first network entity to the second network entity which is stored by the second network entity as the context information of the second network entity and using the stored context information at the mobile terminal and the second network entity for compression and decompression of the headers of the packets.

THE REFERENCES

The Examiner relies upon the following references as evidence of unpatentability:

Chen	US 6,529,527 B1	Mar. 4, 2003
Maggenti	US 6,477,150 B1	Nov. 5, 2002

THE REJECTION

The following rejection is on appeal before us:

1. Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the teachings of Chen in view of Maggenti.

Rather than repeat the arguments of Appellants or the Examiner, we make reference to the Briefs and the Answer for the respective details thereof.

OPINION

Only those arguments actually made by Appellants have been considered in this decision. It is our view, after consideration of the record

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before us, that the evidence relied upon does not support the Examiner's rejection of the claims on appeal. Accordingly, we reverse.

INDEPENDENT CLAIMS 1 and 12

We consider first the Examiner's rejection of independent claims 1 and 12 as being unpatentable over the teachings of Chen in view of Maggenti.

Appellants argue that the Examiner does not make any argument, or cite either reference [i.e., Chen or Maggenti] as disclosing taking a snapshot of the old compressor and the decompressor context information and delivering it to the new network entity after stopping the context information [updating] (Reply Br. 3).

The Examiner disagrees. The Examiner notes that Chen teaches the packet with its header (i.e., where context information is part of the header) is sent from one base station to another. The Examiner argues it is inherent that updating of any type within a packet must be stopped prior to sending the packets. The Examiner reasons that if packets are not stopped, they cannot have information changed within the packet (such as flags within the headers). In addition, the Examiner asserts that Chen also teaches the use of buffers to store packets if needed prior to sending out the packets. The Examiner concludes that this further indicates that packets (i.e., including header information, such as context information) are stopped prior to being sent out (Answer 16-17).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598

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(Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Furthermore, “‘there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness’ . . . [H]owever, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. ___, 2007 WL 1237837, at *14 (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

We begin our analysis by noting that in the rejection of claims 1 and 12, the Examiner asserts that Chen teaches the limitations argued by Appellants (i.e., “stopping the context information updating . . .” and “taking a snapshot of the compression and decompression context information . . .”) (see Answer 4; see also claim 1). However, when we look to the Examiner’s rejection for specific citations for these argued limitations, there are none (Answer 4, ¶ 1). In responding to Appellants’ arguments, the Examiner asserts that Chen *inherently* teaches “stopping the context information updating” as claimed (see Answer 16). Likewise, the Examiner asserts that Chen *inherently* teaches “taking a snapshot of the compression and decompression context information,” as claimed. (See Answer 18, ¶ 2: 8-10,

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i.e., “It is inherent that a snapshot can only be taken when all the data has been received as claimed. Otherwise, the snapshot would be useless”).

After carefully considering both the Chen and Maggenti references, we find no specific teaching or suggestion within either reference that fairly meets the language of the claim that requires “stopping the context information updating...,” and “taking a snapshot of the compression and decompression context information ...” (claim 1). We find that to affirm the Examiner on this record would require speculation on our part.

Furthermore, the Court of Appeals for the Federal Circuit has determined that inherency may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (internal citations omitted). Because we find the combination of Chen and Maggenti fails to teach or suggest all the limitations recited in the claim, we agree with Appellants that the Examiner has failed to meet the burden of presenting a prima facie case of obviousness. Accordingly, we will reverse the Examiner’s rejection of independent claim 1 as being unpatentable over Chen in view of Maggenti.

Because independent claim 12 recites equivalent limitations, we will also reverse the Examiner’s rejection of claim 12 as being unpatentable over Chen in view of Maggenti for the same reasons discussed *supra* with respect to claim 1. Because we have reversed the Examiner’s rejection of each independent claim, we will not sustain the Examiner’s rejection of any dependent claims under appeal. Therefore, we also reverse the Examiner’s

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rejection of dependent claims 2-11 and 13-21 as being unpatentable over
Chen in view of Maggenti.

DECISION

In summary, we will not sustain the Examiner's rejection of any
claims under appeal. Therefore, the decision of the Examiner rejecting
claims 1-21 is reversed.

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REVERSED

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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GURPREET S. AHLUWALIA
and DOUGLAS SHANDER

Appeal No. 1997-1717
Application No. 08/068,256

ON BRIEF

Before WINTERS, ROBINSON, and ADAMS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 8 through 12. Claim 2 stands objected to and "would be allowable if rewritten in independent form" (final rejection, Paper No. 13, page 2). Claims 3 through 7, the only other claims pending in the application, have been withdrawn from further consideration under 37 CFR § 1.142(b) as not readable on the elected claims.

Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

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1. A process of reducing mammalian hair growth, comprising
selecting an area of skin from which reduced hair growth is desired, and
applying to said area of skin a composition including an inhibitor of lipoxygenase in an amount effective to reduce hair growth. 5-

The references relied on by the examiner are:

Shander (Shander I)	4,720,489	Jan. 19, 1988
Breuer et al. (Breuer)	4,885,289	Dec. 5, 1989
Shander et al. (Shander II)	5,132,293	Jul. 21, 1992

Ground of Rejection

Claims 1 and 8 through 12 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Breuer, Shander I and Shander II.¹

We reverse the examiner's rejection. In addition, we remand this application to the examiner for consideration of U.S. Patent No. 5,928,654, brought to our attention in a communication filed June 9, 2000 (Paper No. 29). We also remand so that the examiner may consider this application in tandem with Application No. 08/068,257.

¹ The examiner withdrew the final rejection of claims 1 and 8 through 12 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure (examiner's answer, page 2, § (4)).

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Background

The present invention is directed to a process of reducing mammalian hair growth by applying to the skin a composition including an inhibitor of 5-lipoxygenase (specification, page 1, lines 12-15). Appellants state that they “conceived that inhibiting the enzyme 5-lipoxygenase would reduce the rate of hair growth” (appeal brief, page 3). According to appellants, “[e]very inhibitor of 5-lipoxygenase that applicants tested caused a reduction in hair growth.” (Id.)

Discussion

I. Rejection under 35 U.S.C. § 103

All of the appealed claims stand rejected under 35 U.S.C. § 103 as unpatentable over Breuer, Shander I and Shander II. After careful consideration of the record, we will not sustain this rejection.

The examiner argues that all three references “disclose a number of structures which are useful in inhibiting hair growth” (examiner’s answer, page 4). According to the examiner, “[w]hile none of the compounds of the prior art are identified as 5-lipoxygenase inhibitors they would render the instantly claimed process obvious if they possessed any such activity” (Id.) (emphasis added). The examiner places the burden on appellants to show that the prior art compounds are “completely inactive” as 5-lipoxygenase inhibitors (Id.). We disagree with this line of reasoning.

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As stated in In re Best, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977), quoting from In re Swinehart, 439 F.2d 210, 212-33, 169 USPQ 226, 229 (CCPA 1971):

[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

This burden was involved in In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), and is applicable to product and process claims reasonably considered as possessing the allegedly inherent characteristics. In re Best, 562 F.2d at 1255, 195 USPQ at 433. On the particular facts of this case, however, the examiner has not shown sound basis for believing that the prior art compounds possess 5-lipoxygenase inhibiting activity. Unlike the situation presented in Best, the examiner has not set forth "reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter [5-lipoxygenase inhibiting activity] may, in fact, be an inherent characteristic of the prior art." Accordingly, the examiner is not in position to invoke the above-quoted rule of law enunciated in Best and cases cited therein.

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The examiner's position is speculative in nature; it is devoid of factual support or adequate reasoning. Simply stated, it is not enough to speculate that the prior art compounds may possess 5-lipoxygenase inhibiting activity and, based on speculation alone, shift the burden of persuasion to appellants to establish that these compounds are "completely inactive" as 5-lipoxygenase inhibitors. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). On this record, the examiner cannot require appellants "to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on."

Having found that the examiner has not established a prima facie case of obviousness of the appealed claims, we find it unnecessary to discuss the declaration of Dr. Ahluwalia submitted on July 14, 1995 (attachment to Paper No. 11) and relied on by appellants to rebut any such prima facie case.

The examiner's rejection of claims 1 and 8 through 12 under 35 U.S.C. § 103 is reversed.

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II. Remand to Consider U.S. Patent No. 5,928,654

On June 9, 2000, appellants filed a communication identifying a number of references that should be brought to the examiner's attention (Paper No. 29). U.S. Patent No. 5,928,654 to Duranton (Duranton) is cited among those references. This patent is directed to the conjoint use of a lipoxygenase inhibitor and a cyclooxygenase inhibitor in a process for reducing hair growth (see Duranton, claim 1). The claims under appeal, written in open language, would appear to "read on" the subject matter set forth in the claims of Duranton. In addition, Duranton appears to disclose a number of appellants' preferred lipoxygenase inhibitors (Duranton, col. 4, lines 26-32, 51-59).

We note that Duranton was filed on April 14, 1997, almost four years after the filing date of this application. Thus, Duranton is not prior art against appellants. Appellants argue that the claims in Duranton were not rejected on the grounds advanced against their claims. Appellants argue, therefore, that there has been an apparent inconsistency in the way applications drawn to similar subject matter have been prosecuted.

In light of our reversal of the rejection of claims 1 and 8 through 12 under 35 U.S.C. § 103, and in light of the issuance of U.S. Patent No. 5,928,654, we remand this application to the examiner so that he may compare the two sets of claims and take further action as deemed appropriate. A copy of U.S. Patent No. 5,928,654 is enclosed with the opinion.

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III. Recommendation to Consider Related Application No. 08/068,257

Appellants invite attention to a related appeal in Application No. 08/068,257, involving the enzyme cyclooxygenase (appeal brief, paragraph bridging pages 2-3). Appellants state that the issues in both appeals are "substantially the same" (appeal brief, page 1). According to PTO records, Application No. 08/068,257 is currently awaiting action by the examiner.

In view of appellants' statements, we remand this application to the examiner so that it may be considered in tandem with Application No. 08/068,257. We recommend that the examiner consider the relationship of the claims in this application to the claims

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in Application No. 08/068,257, and in Duranton, for further action as deemed appropriate.

REVERSED and REMANDED

Sherman D. Winters)	
Administrative Patent Judge)	
)	BOARD OF PATENT
)	
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

SDW/cam

ROBERT C. NABINGER

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